

## TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

LSA Document #08-61(F)

### DIGEST

Amends 410 IAC 15-1.1-8, 410 IAC 15-1.1-11, 410 IAC 15-1.1-13.3, 410 IAC 15-1.1-22, 410 IAC 15-1.4-2.2, 410 IAC 15-2.4-2.2, 410 IAC 26-1-12.5, 410 IAC 26-1-17.8, 410 IAC 26-6-2, 410 IAC 27-1-13.5, 410 IAC 27-1-15, 410 IAC 27-1-23, and 410 IAC 27-6-2 to update and modify the reporting of serious adverse events. Repeals 410 IAC 15-1.1-13.5, 410 IAC 26-1-12.7, and 410 IAC 27-1-13.7. Effective 30 days after filing with the Publisher.

SECTION 1. 410 IAC 15-1.1-8 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 15-1.1-8 "Donor" defined**

Authority: IC 16-21-1-7

Affected: IC 16-21-1; IC 29-2-16.1-1

Sec. 8. "Donor" means an individual as defined in ~~IC 29-2-16.1~~ **IC 29-2-16.1-1**.  
(Indiana State Department of Health; 410 IAC 15-1.1-8; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

SECTION 2. 410 IAC 15-1.1-11 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 15-1.1-11 "Health care provider" defined**

Authority: IC 16-21-1-7

Affected: IC 16-18-2-163; IC 16-21-1

Sec. 11. "Health care provider" means a provider as defined in ~~IC 27-12-2-14~~ **IC 16-18-2-163**.  
(Indiana State Department of Health; 410 IAC 15-1.1-11; filed Dec 21, 1994, 9:40 a.m.: 18 IR 1262; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)

SECTION 3. 410 IAC 15-1.1-13.3 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 15-1.1-13.3 "Immediately postoperative" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 13.3. "Immediately postoperative" means within twenty-four (24) hours after either of the following:

(1) ~~Induction~~ **Administration** of anesthesia (if surgery or other invasive procedure is not completed).

(2) Completion of surgery or other invasive procedure.

*(Indiana State Department of Health; 410 IAC 15-1.1-13.3; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

SECTION 4. 410 IAC 15-1.1-22 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 15-1.1-22 "Surgery or other invasive procedure" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 22. For purposes of this rule, 410 IAC 15-1.4-2.2, and 410 IAC 15-2.4-2.2, "surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. **Such A procedure ends when the surgical incision has been closed or operative devices, such as probes, have been removed. The** procedures include, but are not limited to, **the following:**

- (1) Open or percutaneous surgical procedures.
- (2) Percutaneous aspiration.
- (3) Selected injections.
- (4) Biopsy.
- (5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
- (6) Laparoscopies.
- (7) Endoscopies.
- (8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters.

*(Indiana State Department of Health; 410 IAC 15-1.1-22; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

SECTION 5. 410 IAC 15-1.4-2.2 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 15-1.4-2.2 Reportable events**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2.2. (a) The hospital's quality assessment and improvement program under section 2 of this rule shall include the following:

(1) A process for determining the occurrence of the following ~~serious adverse~~ **reportable** events within the hospital:

(A) The following surgical events:

- (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
    - (AA) that occur in the course of surgery; or
    - (BB) whose exigency precludes obtaining informed consent; or both.
  - (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.
  - (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
    - (AA) that occur in the course of surgery; or
    - (BB) whose exigency precludes obtaining informed consent; or both.
  - (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
    - (AA) Objects intentionally implanted as part of a planned intervention.
    - (BB) Objects present before surgery that were intentionally retained.
    - (CC) ~~Retention of broken~~ **Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.**
  - (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
- (B) The following product or device events:
- (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the hospital. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.
  - (ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:
    - (AA) Catheters.
    - (BB) Drains and other specialized tubes.
    - (CC) Infusion pumps.
    - (DD) Ventilators.
  - (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the hospital. Excluded are deaths **or serious disability** associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
- (C) The following patient protection events:
- (i) Infant discharged to the wrong person.
  - (ii) Patient death or serious disability associated with patient elopement.
  - (iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the hospital, defined as events that result from patient actions after admission to the hospital. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the hospital.

(D) The following care management events:

(i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:

- (AA) drug;
- (BB) dose;
- (CC) patient;
- (DD) time;
- (EE) rate;
- (FF) preparation; or
- (GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose. **Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.**

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ~~ABO~~ **ABO/HLA** incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the hospital. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

- (AA) Pulmonary or amniotic fluid embolism.
- (BB) Acute fatty liver of pregnancy.
- (CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the hospital.

(v) Death or serious disability (kernicterus) associated with **the failure to identify and treat** hyperbilirubinemia in neonates.

(vi) Stage 3 or Stage 4 pressure ulcers acquired after admission to the hospital. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable ~~due to~~ **because of** the presence of eschar.

(vii) Patient death or serious disability ~~due to~~ **resulting from** joint movement therapy performed in the hospital.

**(viii) Artificial insemination with the wrong donor sperm or wrong egg.**

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the hospital. Excludes events involving planned treatment, such as electrical countershock **or elective cardioversion.**

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

- (AA) contains the wrong gas; or
- (BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the hospital.

(iv) Patient death **or serious disability** associated with a fall while being cared for in the hospital.

(v) Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the hospital.

(F) The following criminal events:

- (i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- (ii) Abduction of a patient of any age.
- (iii) Sexual assault on a patient within or on the grounds of the hospital.
- (iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the hospital.

(2) A process for reporting to the department each ~~serious-adverse~~ **reportable** event listed in subdivision (1) that is determined by the hospital's quality assessment and improvement program to have occurred within the hospital.

(b) Subject to subsection (e), the process for determining the occurrence of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) by the hospital's quality assessment and improvement program shall be designed by the hospital to accurately determine the occurrence of any of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) within the hospital in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

- (A) be made to the department;
- (B) be submitted not later than fifteen (15) working days after the ~~serious-adverse~~ **reportable** event is determined to have occurred by the hospital's quality assessment and improvement program;
- (C) be submitted not later than ~~six (6)~~ **four (4)** months after the potential **reportable** event is brought to the program's attention; and
- (D) identify the ~~serious-adverse~~ **reportable** event, **the quarter of occurrence**, and the hospital, but shall not include any identifying information for any:
  - (i) patient;
  - (ii) individual licensed under IC 25; or
  - (iii) hospital employee involved;or any other information.

(2) A ~~potentially~~ **potential** reportable ~~serious-adverse~~ event may be identified by a hospital that:

- (A) receives a patient as a transfer; ~~from another health care facility subject to a serious adverse event requirement~~ or
- (B) admits a patient subsequent to discharge; ~~from another health care facility subject to a serious-adverse reportable event requirement.~~ In the event that a hospital identifies a ~~potentially~~ **potential** reportable event originating from another health care facility subject to a ~~serious-adverse~~ **reportable** event requirement, the identifying hospital shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a ~~serious-adverse~~ reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The hospital's report of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of ~~such-serious adverse~~ **reportable** events occurring within each hospital. The department's public report will be issued ~~no less frequently than~~ annually.

(e) Any ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) that:

(1) is determined to have occurred within the hospital between:

(A) January 1, ~~2006~~; **2009**; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule.

*(Indiana State Department of Health; 410 IAC 15-1.4-2.2; filed Nov 16, 2006, 4:01 p.m.: 20061213-IR-410050193FRA; errata filed Dec 29, 2006, 1:53 p.m.: 20070117-IR-410050193ACA; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA)*

SECTION 6. 410 IAC 15-2.4-2.2 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 15-2.4-2.2 Reportable events**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2.2. (a) The center's quality assessment and improvement program under section 2 of this rule shall include the following:

(1) A process for determining the occurrence of the following ~~serious-adverse~~ **reportable** events within the center:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;  
or both

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;  
or both

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

- (BB) Objects present before surgery that were intentionally retained.
- (CC) ~~Retention of broken~~ **Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.**
- (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
- (B) The following product or device events:
  - (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.
  - (ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:
    - (AA) Catheters.
    - (BB) Drains and other specialized tubes.
    - (CC) Infusion pumps.
    - (DD) Ventilators.
  - (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths **or serious disability** associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
- (C) The following patient protection events:
  - (i) Infant discharged to the wrong person.
  - (ii) Patient death or serious disability associated with patient elopement.
  - (iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.
- (D) The following care management events:
  - (i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:
    - (AA) drug;
    - (BB) dose;
    - (CC) patient;
    - (DD) time;
    - (EE) rate;
    - (FF) preparation; or
    - (GG) route of administration.Excluded are reasonable differences in clinical judgment on drug selection and dose. **Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.**
  - (ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of **ABO ABO/HLA** incompatible blood or blood products.

- (iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:
    - (AA) Pulmonary or amniotic fluid embolism.
    - (BB) Acute fatty liver of pregnancy.
    - (CC) Cardiomyopathy.
  - (iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.
  - (v) Death or serious disability (kernicterus) associated with **the failure to identify and treat** hyperbilirubinemia in neonates.
  - (vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable ~~due to~~ **because of** the presence of eschar.
  - (vii) Patient death or serious disability ~~due to~~ **resulting from** joint movement therapy performed in the center.
  - (viii) **Artificial insemination with the wrong donor sperm or wrong egg.**
- (E) The following environmental events:
- (i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock **or elective cardioversion.**
  - (ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:
    - (AA) contains the wrong gas; or
    - (BB) is contaminated by toxic substances.
  - (iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.
  - (iv) Patient death **or serious disability** associated with a fall while being cared for in the center.
  - (v) Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the center.
- (F) The following criminal events:
- (i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
  - (ii) Abduction of a patient of any age.
  - (iii) Sexual assault on a patient within or on the grounds of the center.
  - (iv) Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.
- (2) A process for reporting to the department each ~~serious-adverse~~ **reportable** event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.
- (b) Subject to subsection (e), the process for determining the occurrence of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) within the center in a timely manner.



(c) Subject to subsection (e), the process for reporting the occurrence of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

- (A) be made to the department;
- (B) be submitted not later than fifteen (15) working days after the ~~serious-adverse~~ **reportable** event is determined to have occurred by the center's quality assessment and improvement program;
- (C) be submitted not later than ~~six (6)~~ **four (4)** months after the potential **reportable** event is brought to the program's attention; and
- (D) identify the ~~serious-adverse~~ **reportable** event, **the quarter of occurrence**, and the center, but shall not include any identifying information for any:
  - (i) patient;
  - (ii) individual licensed under IC 25; or
  - (iii) center employee involved;or any other information.

(2) A ~~potentially~~ **potential** reportable ~~serious-adverse~~ event may be identified by a center that:

- (A) receives a patient as a transfer; ~~from another health care facility subject to a serious adverse event requirement~~ or
- (B) admits a patient subsequent to discharge; ~~from another health care facility subject to a serious-adverse reportable event requirement.~~ In the event that a center identifies a ~~potentially~~ **potential** reportable event originating from another health care facility subject to a ~~serious-adverse reportable event requirement~~, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a ~~serious-adverse~~ reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The center's report of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of ~~such serious adverse reportable~~ events occurring within each center. The department's public report will be issued ~~not less frequently than annually~~.

(e) Any ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) that:

(1) is determined to have occurred within the center between:

- (A) January 1, ~~2006~~; **2009**; and
- (B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule.

*(Indiana State Department of Health; 410 IAC 15-2.4-2.2; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 7. 410 IAC 26-1-12.5 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 26-1-12.5 "Immediately postoperative" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 12.5. "Immediately postoperative" means within twenty-four (24) hours after either of the following:

(1) ~~Induction~~ **Administration** of anesthesia (if surgery or other invasive procedure is not completed).

(2) Completion of surgery or other invasive procedure.

*(Indiana State Department of Health; 410 IAC 26-1-12.5; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 8. 410 IAC 26-1-17.8 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 26-1-17.8 "Surgery or other invasive procedure" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 17.8. "Surgery or other invasive procedure", for purposes of 410 IAC 26-6-2, means surgical or other invasive procedures that ~~involves~~ **involve** a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. ~~Such~~ **A procedure ends when the surgical incision has been closed or operative devices such as probes have been removed.** The procedures include, but are not limited to, **the following:**

(1) Open or percutaneous surgical procedures.

(2) Percutaneous aspiration.

(3) Selected injections.

(4) Biopsy.

(5) Percutaneous cardiac and vascular diagnostic or interventional procedures.

(6) Laparoscopies.

(7) Endoscopies.

(8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contrast agents.

*(Indiana State Department of Health; 410 IAC 26-1-17.8; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 9. 410 IAC 26-6-2 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 26-6-2 Reportable events**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2. (a) The clinic's quality assessment and improvement program under section 1 of this rule shall include the following:

(1) A process for determining the occurrence of the following ~~serious-adverse~~ **reportable** events within the clinic:

(A) The following surgical events:

(i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;  
or both.

(ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

(iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

(AA) that occur in the course of surgery; or

(BB) whose exigency precludes obtaining informed consent;  
or both.

(iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:

(AA) Objects intentionally implanted as part of a planned intervention.

(BB) Objects present before surgery that were intentionally retained.

(CC) ~~Retention of broken~~ **Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.**

(v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.

(B) The following product or device events:

(i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the clinic. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.

(ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:

(AA) Catheters.

(BB) Drains and other specialized tubes.

(CC) Infusion pumps.

(DD) Ventilators.

(iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the clinic. Excluded are deaths **or serious disability** associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(C) The following patient protection events:

(i) Infants discharged to the wrong person.

- (ii) Patient death or serious disability associated with patient elopement.
  - (iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the clinic, defined as events that result from patient actions after admission to the clinic. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the clinic.
- (D) The following care management events:
- (i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:
    - (AA) drug;
    - (BB) dose;
    - (CC) patient;
    - (DD) time;
    - (EE) rate;
    - (FF) preparation; or
    - (GG) route of administration.Excluded are reasonable differences in clinical judgment on drug selection and dose. **Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.**
  - (ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of **ABO/HLA** incompatible blood or blood products.
  - (iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the clinic. Included are events that occur within forty-two (42) days post-delivery. Excluded are deaths from any of the following:
    - (AA) Pulmonary or amniotic fluid embolism.
    - (BB) Acute fatty liver of pregnancy.
    - (CC) Cardiomyopathy.
  - (iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the clinic.
  - (v) Death or serious disability (kernicterus) associated with **the failure to identify and treat** hyperbilirubinemia in neonates.
  - (vi) Stage 3 or 4 pressure ulcers acquired after admission to the clinic. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable ~~due to~~ **because of** the presence of eschar.
  - (vii) Patient death or serious disability ~~due to~~ **resulting from** joint movement therapy performed in the clinic.
  - (viii) **Artificial insemination with the wrong donor sperm or wrong egg.**
- (E) The following environmental events:
- (i) Patient death or serious disability associated with an electric shock while being cared for in the clinic. Excluded are events involving planned treatment, such as electrical countershock **or elective cardioversion.**
  - (ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:
    - (AA) contains the wrong gas; or
    - (BB) is contaminated by toxic substances.

- (iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the clinic.
  - (iv) Patient death **or serious disability** associated with a fall while being cared for in the clinic.
  - (v) Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the clinic.
- (F) The following criminal events:
- (i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
  - (ii) Abduction of a patient of any age.
  - (iii) Sexual assault on a patient within or on the grounds of the clinic.
  - (iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the clinic.
- (2) A process for reporting to the department each ~~serious-adverse~~ **reportable** event listed in subdivision (1) that is determined by the clinic's quality assessment and improvement program to have occurred within the clinic.
- (b) Subject to subsection (e), the process for determining the occurrence of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) by the clinic's quality assessment and improvement program shall be designed by the clinic to accurately determine the occurrence of any of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) within the clinic in a timely manner.
- (c) Subject to subsection (e), the process for reporting the occurrence of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall comply with the following:
- (1) The report shall:
- (A) be made to the department;
  - (B) be submitted not later than fifteen (15) working days after the ~~serious-adverse~~ **reportable** event is determined to have occurred by the clinic's quality assessment and improvement program;
  - (C) be submitted not later than ~~six (6)~~ **four (4)** months after the potential **reportable** event is brought to the program's attention; and
  - (D) identify the ~~serious-adverse~~ **reportable** event, **the quarter of occurrence**, and the clinic, but shall not include any identifying information for any:
    - (i) patient;
    - (ii) individual licensed under IC 25; or
    - (iii) clinic employee involved;or any other information.
- (2) A ~~potentially~~ **potential** reportable ~~serious-adverse~~ event may be identified by a clinic that:
- (A) receives a patient as a transfer; ~~from another health care facility subject to a serious-adverse event requirement~~ or
  - (B) admits a patient subsequent to discharge; ~~from another health care facility subject to a serious-adverse reportable event requirement~~. In the event that a clinic identifies a ~~potentially~~ **potential** reportable event originating from another health care facility subject to a ~~serious-adverse~~ **reportable** event requirement, the identifying clinic shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a ~~serious-adverse~~ reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The clinic's report of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of ~~such-serious adverse~~ **reportable** events occurring within each clinic. The department's public report will be issued ~~not less frequently than~~ annually.

(e) Any ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) that:

(1) is determined to have occurred within the clinic between:

(A) January 1, ~~2006~~; **2009**; and

(B) the effective date of this rule; and

(2) has not been previously reported;

must be reported within five (5) days of the effective date of this rule.

*(Indiana State Department of Health; 410 IAC 26-6-2; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 10. 410 IAC 27-1-13.5 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 27-1-13.5 "Immediately postoperative" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 13.5. "Immediately postoperative" means within twenty-four (24) hours after either of the following:

(1) ~~Induction~~ **Administration** of anesthesia (if surgery or other invasive procedure is not completed).

(2) Completion of surgery or other invasive procedure.

*(Indiana State Department of Health; 410 IAC 27-1-13.5; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 11. 410 IAC 27-1-15 IS AMENDED TO READ AS FOLLOWS:

#### **410 IAC 27-1-15 "Licensed practical nurse" defined**

Authority: IC 16-21-1-7; IC 16-21-2-2.5

Affected: IC 16-21-1; IC 25-23-1-1.2

Sec. 15. "Licensed practical nurse" has the meaning set forth in ~~IC 23-23-1-1.2~~ **IC 25-23-1-1.2**. *(Indiana State Department of Health; 410 IAC 27-1-15; filed Feb 3, 2006, 2:00 p.m.: 29 IR 1905)*

SECTION 12. 410 IAC 27-1-23 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 27-1-23 "Surgery or other invasive procedure" defined**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1

Sec. 23. "Surgery or other invasive procedure" means, for purposes of 410 IAC 27-6-2, surgical or other invasive procedures that ~~involves~~ **involve** a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. ~~Such~~ **A procedure ends when the surgical incision has been closed or operative devices such as probes have been removed.** The procedures include, but are not limited to, **the following:**

- (1) Open or percutaneous surgical procedures.
- (2) Percutaneous aspiration.
- (3) Selected injections.
- (4) Biopsy.
- (5) Percutaneous cardiac and vascular diagnostic or interventional procedures.
- (6) Laparoscopies.
- (7) Endoscopies.
- (8) Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, or diagnostic tests without intravenous contract agents.

*(Indiana State Department of Health; 410 IAC 27-1-23; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 13. 410 IAC 27-6-2 IS AMENDED TO READ AS FOLLOWS:

**410 IAC 27-6-2 Reportable events**

Authority: IC 16-19-3-4; IC 16-21-1-7

Affected: IC 16-19-3; IC 16-21-1; IC 25

Sec. 2. (a) The center's quality assessment and improvement program under section 1 of this rule shall include the following:

- (1) A process for determining the occurrence of the following ~~serious-adverse~~ **reportable** events within the center:

(A) The following surgical events:

- (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:

- (AA) that occur in the course of surgery; or
- (BB) whose exigency precludes obtaining informed consent;
- or both.

- (ii) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.

- (iii) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations:
    - (AA) that occur in the course of surgery; or
    - (BB) whose exigency precludes obtaining informed consent; or both.
  - (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded:
    - (AA) Objects intentionally implanted as part of a planned intervention.
    - (BB) Objects present before surgery that were intentionally retained.
    - (CC) **Retention of broken Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.**
  - (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
- (B) The following product or device events:
- (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.
  - (ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following:
    - (AA) Catheters.
    - (BB) Drains and other specialized tubes.
    - (CC) Infusion pumps.
    - (DD) Ventilators.
  - (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center. Excluded are deaths **or serious disability** associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
- (C) The following patient protection events:
- (i) Infant discharged to the wrong person.
  - (ii) Patient death or serious disability associated with patient elopement.
  - (iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center. Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.
- (D) The following care management events:
- (i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong:
    - (AA) drug;
    - (BB) dose;
    - (CC) patient;
    - (DD) time;
    - (EE) rate;



- (FF) preparation; or
- (GG) route of administration.

Excluded are reasonable differences in clinical judgment on drug selection and dose. **Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.**

(ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ~~ABO~~ **ABO/HLA** incompatible blood or blood products.

(iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center. Included are events that occur within forty-two (42) days postdelivery. Excluded are deaths from any of the following:

- (AA) Pulmonary or amniotic fluid embolism.
- (BB) Acute fatty liver of pregnancy.
- (CC) Cardiomyopathy.

(iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.

(v) Death or serious disability (kernicterus) associated with **the failure to identify and treat** hyperbilirubinemia in neonates.

(vi) Stage 3 or 4 pressure ulcers acquired after admission to the center. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable ~~due to~~ **because of** the presence of eschar.

(vii) Patient death or serious disability ~~due to~~ **resulting from** joint movement therapy performed in the center.

**(viii) Artificial insemination with the wrong donor sperm or wrong egg.**

(E) The following environmental events:

(i) Patient death or serious disability associated with an electric shock while being cared for in the center. Excluded are events involving planned treatment, such as electrical countershock **or elective cardioversion.**

(ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient:

- (AA) contains the wrong gas; or
- (BB) is contaminated by toxic substances.

(iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.

(iv) Patient death **or serious disability** associated with a fall while being cared for in the center.

(v) Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the center.

(F) The following criminal events:

(i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(ii) Abduction of a patient of any age.

(iii) Sexual assault on a patient within or on the grounds of the center.

(iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the center.

(2) A process for reporting to the department each ~~serious-adverse~~ **reportable** event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.

(b) Subject to subsection (e), the process for determining the occurrence of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the ~~serious-adverse~~ **reportable** events listed in subsection (a)(1) within the center in a timely manner.

(c) Subject to subsection (e), the process for reporting the occurrence of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:

(A) be made to the department;

(B) be submitted not later than fifteen (15) working days after the ~~serious-adverse~~ **reportable** event is determined to have occurred by the center's quality assessment and improvement program;

(C) be submitted not later than ~~six (6)~~ **four (4)** months after the potential **reportable** event is brought to the program's attention; and

(D) identify the ~~serious-adverse~~ **reportable** event, **the quarter of occurrence**, and the center, but shall not include any identifying information for any:

(i) patient;

(ii) individual licensed under IC 25; or

(iii) center employee involved;

or any other information.

(2) A ~~potentially~~ **potential** reportable ~~serious-adverse~~ event may be identified by a center that:

(A) receives a patient as a transfer; ~~from another health care facility subject to a serious adverse event requirement~~ or

(B) admits a patient subsequent to discharge;

from another health care facility subject to a ~~serious-adverse~~ **reportable** event requirement. In the event that a center identifies a ~~potentially~~ **potential** reportable event originating from another health care facility subject to a ~~serious-adverse~~ **reportable** event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a ~~serious-adverse~~ reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The center's report of a ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of ~~such serious adverse~~ **reportable** events occurring within each center. The department's public report will be issued ~~not less frequently than~~ annually.

(e) Any ~~serious-adverse~~ **reportable** event listed in subsection (a)(1) that:

(1) is determined to have occurred within the center between:

(A) January 1, 2006; 2009; and

(B) the effective date of this rule; and  
(2) has not been previously reported;  
must be reported within five (5) days of the effective date of this rule.  
*(Indiana State Department of Health; 410 IAC 27-6-2; filed Nov 21, 2006, 7:20 a.m.: 20061220-IR-410050321FRA)*

SECTION 14. THE FOLLOWING ARE REPEALED: 410 IAC 15-1.1-13.5; 410 IAC 26-1-12.7; 410 IAC 27-1-13.7.